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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,397	08/14/2003	Michael S. H. Chu	MIY-P02-024	9451
7590	03/06/2006		EXAMINER POUS, NATALIE R	
Patent Group Ropes & Gray LLP One International Place Boston, MA 02110			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,397	CHU ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/22/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application Nos. 60/286863, 60/274843, 10/093424, 10/093398, 10/093371, 60/449465, 60/434167, 60/418827, 60/418642, 60/403555 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The earliest listed application with sufficient for compliance is 60/465722, filed 04/25/2003. The priority filing date for this application is therefore 04/25/2003.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-4, 6, 9-14, 17, 19-22, 24, 26-28, 31, 33-38, 40, 43-48, 51, 53, 54, 57-59 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. (US 6911003).

Regarding Claim 1, Anderson teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a handle (64), and a shaft (60) having proximal (52) and distal (58) ends and shaped to describe a plurality of curves substantially in a single plane along its length (fig. 2), the proximal end of the shaft being attached to the handle (fig. 5).

Regarding Claim 2, Anderson teaches the delivery device of claim 1, wherein the distal end of the shaft includes a substantially straight portion (60a) bent at an angle relative to the shaft (60).

Regarding Claim 3, Anderson teaches the delivery device of claim 2, wherein the angle is determined to accommodate a pubic bone of a patient (fig. 11).

Regarding Claim 4, Anderson teaches the delivery device of claim 2, wherein the bend is in a direction toward a pubic bone of a patient to reduce likelihood of inadvertently puncturing internal organs (Column 9, proximate lines 7-20).

Regarding Claim 6, Anderson teaches the delivery device of claim 2, wherein the angle relative to the shaft is greater than about 90 degrees (fig. 1).

Regarding Claim 9, Anderson teaches the delivery device of claim 1, wherein at least one of the curves describes an arc of greater than about 45 degrees (angle between portions 60b and 60c).

Regarding Claim 10, Anderson teaches the delivery device of claim 1, wherein at least one of the plurality of curves describes an arc of greater than about 60 degrees (angle between portions 60b and 60c).

Regarding Claim 11, Anderson teaches the delivery device of claim 1, wherein at least one of the plurality of curves describes an arc of greater than about 90 degrees (angle between portions 60b and 60c).

Regarding Claim 12, Anderson teaches the delivery device of claim 1, wherein the handle and the shaft are reversibly attached (fig. 2).

Regarding Claim 13, Anderson teaches the delivery device of claim 1, including a connector (58) located at the distal end of the shaft for attaching to an end of the implant (46).

Regarding Claim 14, Anderson teaches the delivery device of claim 13, wherein the connector (58) is formed integral to the shaft (60).

Regarding Claim 17, Anderson teaches the delivery device of claim 13, wherein the connector includes a plug portion (58) for interfitting with a receptacle (56) on the end of the implant.

Regarding Claim 19, Anderson teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a handle (64), and a shaft (60) having proximal and distal ends, the proximal end being connected to the handle (fig. 5) and the distal end including a substantially straight portion (60a) bent at an angle relative to the shaft.

Regarding Claim 20, Anderson teaches the delivery device of claim 19, wherein the distal end of the shaft includes a substantially straight portion bent at an angle relative to the shaft and the bend being located along about a distal most 25% of the shaft (fig. 1).

Regarding Claim 21, Anderson teaches the delivery device of claim 20, wherein the angle is determined to accommodate a pubic bone of a patient (fig. 11).

Regarding Claim 22, Anderson teaches the delivery device of claim 20, wherein the bend is in a direction toward a pubic bone of a patient to reduce likelihood of inadvertently puncturing internal organs (Column 9, proximate lines 7-20).

Regarding Claim 24, Anderson teaches the delivery device of claim 20, wherein the angle relative to the shaft is greater than about 90 degrees (fig. 1).

Regarding Claim 26, Anderson teaches the delivery device of claim 19, wherein the handle and the shaft are reversibly attached (fig. 2).

Regarding Claim 27, Anderson teaches the delivery device of claim 19, including a connector (58) located at the distal end of the shaft for attaching to an end of the implant.

Regarding Claim 28, Anderson teaches the delivery device of claim 27, wherein the connector (58) is formed integral to the shaft (60).

Regarding Claim 31, Anderson teaches the delivery device of claim 27, wherein the connector includes a plug portion (58) for interfitting with a receptacle (56) on the end of the implant.

Regarding Claim 33, Anderson teaches a delivery system for delivering an implant to an anatomical site in a body of a patient, the system comprising, an implant (46) having first and second ends, and a delivery device comprising a handle (64), and a shaft (60) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length, the proximal end of the shaft being attached to the handle.

Regarding Claim 34, Anderson teaches the delivery system of claim 33, wherein the implant includes a sling for treating urinary incontinence (Column 9, proximate lines 1-5).

Regarding Claim 35, Anderson teaches the delivery system of claim 34, wherein the sling is configured for placement at a midurethral anatomical site in the body of a patient (fig. 9).

Regarding Claim 36, Anderson teaches the delivery system of claim 33, wherein the distal end of the shaft includes a substantially straight portion bent at an angle relative to the shaft (60a), the bend being located along about a distal most 25% of the shaft (fig. 1).

Regarding Claim 37, Anderson teaches the delivery system of claim 36, wherein the angle is determined to accommodate a pubic bone of a patient (fig. 5).

Regarding Claim 38, Anderson teaches the delivery system of claim 36, wherein the bend is in a direction toward a pubic bone of a patient to reduce likelihood of inadvertently puncturing internal organs (Column 9, proximate lines 1-5).

Regarding Claim 40, Anderson teaches the delivery system of claim 36, wherein the angle relative to the shaft is greater than about 90 degrees (fig. 1).

Regarding Claim 43, Anderson teaches the delivery system of claim 33, wherein at least one of the curves describes an arc of greater than about 45 degrees (angle between portions 60b and 60c).

Regarding Claim 44, Anderson teaches the delivery system of claim 33, wherein at least one of the plurality of curves describes an arc of greater than about 60 degrees (angle between portions 60b and 60c).

Regarding Claim 45, Anderson teaches the delivery system of claim 33, wherein at least one of the plurality of curves describes an arc of greater than about 90 degrees (angle between portions 60b and 60c).

Regarding Claim 46, Anderson teaches the delivery system of claim 33, wherein the handle and the shaft are reversibly attached (fig. 2).

Regarding Claim 47, Anderson teaches the delivery system of claim 33, including a connector (58) located at the distal end of the shaft for attaching to the first end of the implant.

Regarding Claim 48, Anderson teaches the delivery system of claim 47, wherein the connector is formed integral to the shaft (fig. 1).

Regarding Claim 51, Anderson teaches the delivery system of claim 47, wherein the connector includes a plug portion (58) for integrating with a receptacle on the end of the implant (56).

Regarding Claim 53, Anderson teaches a method of delivering an implant to an anatomical site in a body of a patient, the method comprising, inserting into a body of a patient a shaft having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length (fig. 4), attaching the distal end of the shaft to a first end of an implant (fig. 6), and positioning the implant at an anatomical site within the body of the patient (fig. 8).

Regarding Claim 54, Anderson teaches the method of claim 53 comprising inserting the shaft into the body of the patient suprapubically (fig. 4).

Regarding Claim 57, Anderson teaches the method of claim 53, wherein the implant includes a sling (42) for treating urinary incontinence and the method includes positioning the sling at a midurethral location (fig. 10).

Regarding Claim 58, Anderson teaches a method of delivering an implant to an anatomical site in a body of a patient, the method comprising, inserting into a body of a patient a shaft having proximal and distal ends, the proximal end being connected to the handle and the distal end including a substantially straight portion bent at an angle relative to the shaft attaching the distal end of the shaft to a first end of an implant (fig. 4), and positioning the implant at an anatomical site within the body of the patient (fig. 8).

Regarding Claim 59, Anderson teaches the method of claim 58 comprising inserting the shaft into the body of the patient suprapubically (fig. 4).

Regarding Claim 63, Anderson teaches the method of claim 58, wherein the implant includes a sling for treating urinary incontinence and the method includes positioning the sling at a midurethral location (fig. 10).

4. Claims 1,8, 13-16, 19, 27-30, 33, 42 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Giesy et al. (US 5152749).

Regarding Claim 1, Giesy teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a handle (12), and a shaft (20) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length (fig. 7), the proximal end of the shaft being attached to the handle (fig. 2).

Regarding Claim 8, Giesy teaches the delivery device of claim 1, wherein a most distal one of the plurality of curves includes a concave portion (20e) and a convex portion (20d) and the bend is formed toward the concave portion (fig. 7).

Regarding Claim 13, Giesy teaches the delivery device of claim 1, including a connector (20b) located at the distal end of the shaft for attaching to an end of the implant (40).

Regarding Claim 14, Anderson teaches the delivery device of claim 13, wherein the connector (20b) is formed integral to the shaft (20).

Regarding Claim 15, Giesy teaches the delivery device of claim 14, wherein the connector includes a slot (82) formed in the shaft.

Regarding Claim 16, Giesy teaches the delivery device of claim 14, wherein the slot extends from a surface of the shaft radially (82) into the shaft and axially in a distal direction (83) to form a substantially L- shape.

Regarding Claim 19, Giesy teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a handle (12), and a shaft (20) having proximal and distal ends, the proximal end being connected to the handle (fig. 2) and the distal end including a substantially straight portion (20f) bent at an angle relative to the shaft (20e).

Regarding Claim 27, Giesy teaches the delivery device of claim 19, including a connector (20b) located at the distal end of the shaft for attaching to an end of the implant (40).

Regarding Claim 28, Anderson teaches the delivery device of claim 27, wherein the connector (20b) is formed integral to the shaft (20).

Regarding Claim 29, Giesy teaches the delivery device of claim 28, wherein the connector includes a slot (82) formed in the shaft.

Regarding Claim 30, Giesy teaches the delivery device of claim 28, wherein the slot extends from a surface of the shaft radially (82) into the shaft and axially in a distal direction (83) to form a substantially L- shape.

Regarding Claim 33, Giesy teaches a delivery system for delivering an implant to an anatomical site in a body of a patient, the system comprising, an implant (40) having first and second ends, and a delivery device comprising a handle (12), and a shaft (20) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length, the proximal end of the shaft being attached to the handle (fig. 2).

Regarding Claim 42, Giesy teaches the delivery device of claim 33, wherein a most distal one of the plurality of curves includes a concave portion (20e) and a convex portion (20d) and the bend is formed toward the concave portion (fig. 7).

Regarding Claim 47, Giesy teaches the delivery device of claim 33, including a connector (20b) located at the distal end of the shaft for attaching to an end of the implant (40).

Regarding Claim 48, Anderson teaches the delivery device of claim 47, wherein the connector (20b) is formed integral to the shaft (20).

Regarding Claim 49, Giesy teaches the delivery device of claim 48, wherein the connector includes a slot (82) formed in the shaft.

Regarding Claim 50, Giesy teaches the delivery device of claim 48, wherein the slot extends from a surface of the shaft radially (82) into the shaft and axially in a distal direction (83) to form a substantially L- shape.

5. Claims 1, 2, 5, 7, 13, 18, 19, 20, 13, 25, 27, 32, 33, 36, 39, 41, 47 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Raz et al. (US 6691711).

Regarding Claim 1, Raz teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device (fig. 8a) comprising, a handle (24), and a shaft (28) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length (referring to fig. 8, one curve is at the point of character 28, and a second curve is located at the circular close up of the distal end), the proximal end of the shaft being attached to the handle.

Regarding Claim 2, Raz teaches the delivery device of claim 1, wherein the distal end of the shaft includes a substantially straight portion (distal most portion) bent at an angle relative to the shaft (28).

Regarding Claim 5, Raz teaches the delivery device of claim 2, wherein the angle relative to the shaft is about 90 degrees.

Regarding Claim 7, Raz teaches the delivery device of claim 2, wherein the angle relative to the shaft is less than about 90 degrees (it is noted that "about 90 degrees" may be slightly more than 90 degrees, and therefore an angle of 90 degrees is less than about 90 degrees).

Regarding Claim 13, Raz teaches the delivery device of claim 1, including a connector (distal most portion of shaft 28) located at the distal end of the shaft for attaching to an end of the implant.

Regarding Claim 18, Raz teaches the delivery device of claim 13, wherein the connector includes a receptacle portion for interfitting with a mating connector on the end of the implant (Column 4, proximate lines 1-9).

Regarding Claim 19, Raz teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device (fig. 8a) comprising, a handle (24), and a shaft (28) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length (referring to fig. 8, one curve is at the point of character 28, and a second curve is located at the circular close up of the distal end), the proximal end of the shaft being attached to the handle and the distal end including a substantially straight portion (distal most portion) bent at an angle relative to the shaft (28).

Regarding Claim 20, Raz teaches the delivery device of claim 19, wherein the distal end of the shaft includes a substantially straight portion (distal most portion) bent at an angle relative to the shaft (28).

Regarding Claim 23, Raz teaches the delivery device of claim 20, wherein the angle relative to the shaft is about 90 degrees.

Regarding Claim 25, Raz teaches the delivery device of claim 20, wherein the angle relative to the shaft is less than about 90 degrees (it is noted that "about 90

degrees" may be slightly more than 90 degrees, and therefore an angle of 90 degrees is less than about 90 degrees).

Regarding Claim 27, Raz teaches the delivery device of claim 19, including a connector (distal most portion of shaft 28) located at the distal end of the shaft for attaching to an end of the implant.

Regarding Claim 32, Raz teaches the delivery device of claim 27, wherein the connector includes a receptacle portion for interfitting with a mating connector on the end of the implant (Column 4, proximate lines 1-9).

Regarding Claim 33, Raz teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device (fig. 8a) comprising, an implant having first and second ends (column 3, proximate lines 43-55), a handle (24), and a shaft (28) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length (referring to fig. 8, one curve is at the point of character 28, and a second curve is located at the circular close up of the distal end), the proximal end of the shaft being attached to the handle

Regarding Claim 36, Raz teaches the delivery device of claim 19, wherein the distal end of the shaft includes a substantially straight portion bent at an angle relative to the shaft and the bend being located along about a distal most 25% of the shaft (fig. 1).

Regarding Claim 39, Raz teaches the delivery device of claim 36, wherein the angle relative to the shaft is about 90 degrees.

Regarding Claim 41 Raz teaches the delivery device of claim 36, wherein the angle relative to the shaft is less than about 90 degrees (it is noted that "about 90 degrees" may be slightly more than 90 degrees, and therefore an angle of 90 degrees is less than about 90 degrees).

Regarding Claim 47, Raz teaches the delivery device of claim 33, including a connector (distal most portion of shaft 28) located at the distal end of the shaft for attaching to an end of the implant.

Regarding Claim 52, Raz teaches the delivery device of claim 47, wherein the connector includes a receptacle portion for interfitting with a mating connector on the end of the implant (Column 4, proximate lines 1-9).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 55, 56, 60, 61, 62 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson over Petros as a matter of design choice. Anderson teaches all limitations of preceding claims 53 and 58, and further teaches wherein the implant includes a sling (46) with first and second ends for treating urinary incontinence and the method includes positioning the sling in a loop around a midurethral location (fig. 11) with the ends of the sling extending from the midurethral location along an anterior surface of the pubic bone of the patient.

Anderson fails to disclose wherein the shaft is introduced into the body of the patient transvaginally, prepubically or transobturally. Petros teaches an implant delivery device introduced transvaginally (figs. 2-4) The application discloses wherein the same instrument is capable of performing each procedure and the applicant fails to disclose any advantage of using a prepubic or transobtural procedure rather than a suprapubic approach as disclosed by Anderson or transvaginal approach as taught by Petros. Since the applicant has not disclosed that these two methods provide any advantage over the suprapubic procedure, and the device of Anderson is capable of performing a transvaginal approach as taught by Petros, or prepubic or transobtural procedure to place a surgical implant at a midurethral area, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the procedure using the device transvaginally as disclosed by Petros, or prepubically or transobturally as a matter of design choice.


Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
2/21/06


(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
2/28/06